UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,103	09/12/2003	Parminder Singh	2335-0008.22	6566

23980 7590 04/30/2008

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
1400 PAGE MILL ROAD
PALO ALTO, CA 94304-1124

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
04/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,103	SINGH ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/30/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 01/22/2008 and IDS filed 01/30/2008.

Claims 1-59 are pending and included in the prosecution.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5-8, 10, 11, 27-36, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,552,751 (751).

Claim 1 is directed to composition comprising

(1) composition comprising: (a) water swellable polymer, (b) hydrophilic polymer, and (c) oligomer; and

(2) erodible backing.

Claim 50 is directed to method of whitening teeth comprising using said composition.

US '751 disclosed multilayered film preparation that dissolves in body fluid, the film comprises layer comprises 10-80% water soluble polymer, 10-80% water insoluble

polymer, 10-30% plasticizer that reads on the claimed oligomer, and drug, and other layer comprises hydroxypropyl cellulose or ethyl cellulose, which reads on the erodible backing layer (abstract; col.2, lines 66-68; col.4, lines 59-55-63; col.6, lines 20-33, 49-51). The water soluble polymer comprises cellulose acetate, hydroxypropyl cellulose and polyvinyl pyrrolidone; the water insoluble polymer comprises cellulose acetate; and the plasticizer include ethylene glycol, propylene glycol, polyethylene glycol or polypropylene glycol, all currently claimed as oligomer (col.2, lines 12-28). The erosion of the layer made of water insoluble polymer is inherently slower than layer containing water soluble polymers. The time of erosion of the multilayered film is inherent according to the percentage of water soluble, water insoluble, and plasticizers. The ability of the film to absorb water is inherent. Further, the layer that comprises water soluble polymer, water insoluble polymer, and plasticizer in the same ranges as claimed by applicants, such a layer is inherently hydrogel.

Response to Arguments

3. Applicant's arguments filed 01/22/2008 have been fully considered but they are not persuasive. Applicants argue that US '751 does not teach water soluble polymer and water swellable polymer as required by claim 1. Applicants argue that the reference does not teach the backing layer that erode slower than the drug storing layer.

In response to this argument, it is argued that US '751 clearly disclosed the drug storing layer comprising water soluble polymer comprises cellulose acetate, hydroxypropyl cellulose and polyvinyl pyrrolidone which read on hydrophilic polymer;

water insoluble polymer comprises cellulose acetate; and the plasticizer include ethylene glycol, propylene glycol, polyethylene glycol or polypropylene glycol, all currently claimed as oligomer. Therefore, all the elements of the composition of the hydrogel are disclosed by the reference. The time of erosion of the multilayered film is inherent since materials and their properties are inseparable. In any event, the erosion of the film is directed to the intended use of the film that imparts no patentability to composition claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,800,832 ('832) in view of US 4,552,751 ('751).

US '832 teaches erodible pharmaceutical device for application to the mucosal surface, the device comprising one adhesive layer and backing layer (abstract). Both layers are water soluble (col.3, lines 28-33). The adhesive layer comprises one polymer selected from cellulose derivatives, which is water swellable polymer, combined with polymer selected from polyacrylic acid or polyvinyl pyrrolidone, which is water soluble polymer (col.3, lines 34-39; col.5, lines 37-60; example 11). The backing layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose or hydroxypropylmethyl cellulose (col.3, lines 40-45). The residence time of the device depends on the dissolution rate of the water soluble polymers, and the dissolution rate may be adjusted by adjusting the mixed amounts of the polymers, therefore the erosion time of the device claimed by claims 29-36 are expected to be obtained by adjusting the ratios of water soluble and water swellable polymers according to specific intended use (col.4, line 66-col.4, line 5). The film may contain therapeutic agent, flavoring agent and coloring agent (col.7, line6-col.8, line 10). The film contains water, i.e. hydrogel, or can be solid (col.11, table 1, lines 66-67). The device is expected to be capable to absorb water since it contains water swellable materials.

Although US '832 suggested oligomer in backing layer, col.6, lines 63-66, however, US '832 does not teach the oligomer in the adhesive layer as claimed by

claim1, specific cellulose esters claimed by claims 3 and 11, materials of the backing layer other than cellulose as claimed by claims 12-14.

The specific cellulose esters claimed by claims 3 and 11 and the materials of the backing claimed by claims 12-14 do not impart patentability to the claims, absent evidence to the contrary. In any events, US '571 teaches cellulose acetate in dissolvable films, which is the cellulose ester claimed by claims 3 and 11.

US '571 teaches multilayered film preparation that dissolves in body fluid, the film comprises layer comprises 10-80% water soluble polymer, 10-80% water insoluble polymer, 10-30% plasticizer that reads on oligomer, and drug, and other layer comprises hydroxypropyl cellulose or ethyl cellulose (abstract; col.2, lines 66-68; col.4, lines 59-55-63; col.6, lines 20-33, 49-51). The plasticizers, i.e. oligomers, have the advantage of providing soft flexible film and eliminating the disadvantage of physical properties at the administration site by enhancing the release properties of the active agent (col.4, lines 28-37). The water soluble polymer comprises cellulose acetate, hydroxypropyl cellulose and polyvinyl pyrrolidone; the water insoluble polymer comprises cellulose acetate; and the plasticizer include ethylene glycol, propylene glycol, polyethylene glycol or polypropylene glycol (col.2, lines 12-28).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide erodible pharmaceutical device for application to the mucosal surface comprising adhesive layer comprising water swellable polymer and water soluble polymer as disclosed by US '832, and further add 10-30 % of plasticizer selected from ethylene glycol, propylene glycol, polyethylene glycol or polypropylene

glycol as disclosed by US '751, motivated by the teaching of US '751 that such plasticizers have the advantage of providing soft flexible film and eliminating the disadvantage of physical properties at the administration site by enhancing the release properties of the active agent, with reasonable expectation of having erodible pharmaceutical device for application to the mucosal surface comprising adhesive layer comprising water swellable polymer, water soluble polymer and plasticizer, wherein the device is soft, flexible and has enhanced release properties of the contained active agents.

Response to Arguments

7. Applicant's arguments filed 01/22/2008 have been fully considered but they are not persuasive. Applicants argue that US '832 teaches the disadvantages of the gel, so it teaches away from the present invention. Applicants further argue that no motivation to combine the US '832 with US '751 to form flexible film. Applicants argue that US '832 combined with US '751 does not teach backing that erodes in moisture at a slower rate than hydrogel.

In response to these arguments, it is argued that the disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33,

216 USPQ 1038, 1039 (Fed. Cir 1983). A reference may be relied upon for all that it would have reasonable suggested to one having ordinary skill in the art, including nonpreferred embodiments. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide erodible pharmaceutical device for application to the mucosal surface comprising adhesive layer comprising water swellable polymer and water soluble polymer as disclosed by US '832, and further add 10-30 % of plasticizer selected from ethylene glycol, propylene glycol, polyethylene glycol or polypropylene glycol as disclosed by US '751, motivated by the teaching of US '751 that such plasticizers have the advantage of providing soft flexible film and eliminating the disadvantage of physical properties at the administration site by enhancing the release properties of the active agent, with reasonable expectation of having erodible pharmaceutical device for application to the mucosal surface comprising adhesive layer comprising water swellable polymer, water

soluble polymer and plasticizer, wherein the device is soft, flexible and has enhanced release properties of the contained active agents. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). It has been held that: "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

Further, it s argued that the, the combination of the references is expected to teach backing material that erodes in a slower rate than the hydrogel since the combination teaches backing have the same composition as the claimed and since materials and their properties are inseparable. The time of erosion of the multilayered film is inherent according to the percentage of water soluble, water insoluble, and plasticizers. In any event, the erosion of the film is directed to the untended use of the film that imparts no patentability to composition claims.

8. Claims 42-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '832 and US '751, and further in view of US 5,891,453 ('453).

The combined teachings of US '832 and US '751 are discussed above. However, the combined teachings of the references do not teach teeth whitening material as claimed by claims 42-49, and teeth whitening method as claimed by claims 50-59.

US '453 teaches strip for teeth whitening comprising gel comprising tooth whitening active selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxyacids, and combination thereof (abstract, examples, claim 8).

Hence, the combined teachings of US '832 and US '751 desired to deliver active agent to the mucus membranes and also provided enhanced delivery.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide erodible pharmaceutical device for application to the mucosal surface comprising active agent in adhesive layer comprising water swellable polymer, water soluble polymer and plasticizer as disclosed by the combined teaching of US '832 and US '751, and replace the active agent by teeth whitening agent selected from peroxides and metal chlorites as disclosed by US '453, because US '453 teaches such materials as preferred material for tooth whitening for inclusion in gel strips applied to the mucus membrane, with reasonable expectation of having erodible pharmaceutical device for application to the mucosal surface comprising peroxide or metal chlorite in adhesive layer comprising water swellable polymer, water soluble polymer and plasticizer, that whiten the teeth effectively and safely with great success.

Response to Arguments

9. Applicant's arguments filed 01/22/2008 have been fully considered but they are not persuasive. Applicants argue that there is no specific justification of why combination would have been made.

In response to this argument, it is argued that US '832 and US '751 teach film applied to the mucus membrane, and US '453 teaches tooth whitening for inclusion in gel strips applied to the mucus membrane. Therefore, one having ordinary skill in the art would have been motivated to combine the references because it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG